EXHIBIT 21

From: Al Van Duren
To: Linda Johnsen
CC: holdene@gtlaw.com
Sent: 8/20/2015 9:55:42 PM
Subject: RE: Supporting Data
Attachments: Anesth Analg 2011; 113 1416-21.pdf; Hall presentation 1991.pdf; Memarzadeh 2010 LTE JHI.pdf; MHRA August 7, 2008.pdf; MHRA July 26, 2010.pdf; MHRA June 22, 2010.pdf; Olmstead Poster 2010.pdf; References.docx

Attorney Client Communication

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From: Linda Johnsen
Sent: Wednesday, August 19, 2015 4:44 PM
To: Al Van Duren
Cc: Dave Westlin
Subject: Supporting Data

Al,
Thank you so much.
To be **brief:**

1) Received a number of complaints alleging infections.
2) Within the MDR reporting requirements you are exempt from reporting (Bold Emphasis Mine) based on CFR803.20 (C) (2)

(c) What kind of information reasonably suggests that a reportable event has occurred?
(1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
(2) If you are a user facility, importer, or manufacturer, y **ou do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury** , or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. **Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers.** You must keep in your MDR event files (described in 803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.

3) I have attached a piece provided to me from Dave Westlin that you may want to refer to.

In summary,
Looking for a qualified person article, study or letter that would support decision as noted above.
In addition references (information) that could be referred to.
Thank you for your support.
Linda

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